TITLE: EFFICACY AND SAFETY OF A REMOTE CONDITIONING EXERCISE PROGRAM IN PATIENTS WITH LONG-TERM VENTRICULAR ASSIST DEVICES: THE RE-ACTION-VAD TRIAL.

PATIENT INFORMATION SHEET

PI 143/25

Dated June 9, 2025

STUDY TITLE: EFFICACY AND SAFETY OF A REMOTE CONDITIONING EXERCISE PROGRAM IN PATIENTS WITH LONG-TERM VENTRICULAR ASSIST DEVICES: THE RE-ACTION-VAD TRIAL

INTRODUCTION

You are being invited to participate in a research study. This study has been approved by the Clinical Research Ethics Committee of Hospital Puerta de Hierro Majadahonda in accordance with applicable legislation.

Our intention is to provide you with clear and sufficient information so that you may decide whether or not you wish to participate in this study. Please read this information sheet carefully. After reviewing it, we will address any questions you may have. You may also consult with any person you trust before making your decision.

Please ask the study physician or study staff to clarify any terms or information that you do not fully understand, as well as any other questions that may arise.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. You may choose not to participate or may withdraw your consent at any time without affecting your relationship with your physician or compromising your medical care in any way.

If you decide to participate, you will be asked to sign the attached informed consent form. You will receive a signed and dated copy of this document for your records. The original document will be retained and filed with the rest of the study documentation.

GENERAL DESCRIPTION OF THE STUDY

Patients with long-term ventricular assist devices, such as yourself, frequently experience a significant decline in physical conditioning (deconditioning) for several reasons. These include pre-existing heart failure prior to device implantation, which may have limited exercise capacity in recent years, as well as the sequelae of cardiac surgery.

Major scientific societies recommend that patients such as yourself participate in a structured cardiac rehabilitation exercise program in order to improve functional capacity and quality of life. At Hospital Universitario Puerta de Hierro Majadahonda, we have previously conducted a rehabilitation program in collaboration with Hospital Universitario Ramón y Cajal, achieving positive clinical outcomes and high adherence to scheduled sessions. However, we have observed that up to half of patients with ventricular assist devices have been unable to participate in supervised rehabilitation due to geographical barriers, particularly those residing far from the hospital or in other regions.

Currently, there are no studies evaluating the benefits of home-based exercise delivered through telemedicine (“online”) in patients with ventricular assist devices. For this reason, leading Spanish hospitals with expertise in ventricular assist devices are conducting an internationally pioneering study designed to assess the efficacy and safety of a remote conditioning exercise program specifically tailored for patients with ventricular assist devices.

You are being offered participation in this remote (“online”) rehabilitation program because you are unable to participate in a supervised rehabilitation program, either due to geographical distance from your place of residence or other limitations preventing attendance at this center with the required frequency. If you agree to participate, you could undertake a fully online home-based program, with telemedicine follow-up conducted by our Cardiology team through a mobile application that you may install on your personal device at no cost.

This study aims to compare the remote exercise group with usual standard follow-up care. Assignment to one of the two groups will not be determined by your physician but will be performed by random allocation (randomization). A total of 70 participants are expected to be enrolled. You will have a 50% probability of being assigned to the exercise program group and a 50% probability of being assigned to the usual follow-up group.

If assigned to the exercise program group, the intervention will last 12 weeks. It will include a single initial week of supervised training (the first week of the study). Thereafter, follow-up will continue online until 6 months after study enrollment.

The exercise program will be individualized but generally structured as follows:

- Prescribed warm-up routines (supported by educational videos).
- Respiratory training (5 days per week) using incentive spirometers, which are medical devices designed to improve pulmonary function by promoting sustained deep breathing.
- Walking, treadmill ambulation, or cycling at moderate intensity, consisting of one 30-minute session in the morning and one 30-minute session in the afternoon, at least 3 days per week (ideally 5 days per week).
- Strength training: physiotherapy-guided exercises using light weights (1–2 kg) for upper and lower extremities, 3 days per week.

In addition, a messaging service will be available through the application, allowing communication with the medical team. However, the application must not be used as an emergency contact method.

If you are assigned to the usual follow-up group, you will receive written exercise recommendations, and communication with your medical team will take place through the standard clinical follow-up channels.

All the participants will attend three study visits during the 6-month follow-up period: at baseline (study initiation), at 12 weeks, and at 6 months. Whenever possible, these visits will coincide with your routine cardiology follow-up appointments. During these visits, you will undergo a cardiopulmonary exercise test, a 6-minute walk test, comprehensive laboratory testing, and will complete validated questionnaires assessing quality of life, anxiety, and depression, regardless of the group to which you are assigned. Completion of the questionnaires is expected to take approximately 15 minutes.

POTENTIAL BENEFITS AND RISKS OF PARTICIPATION IN THE STUDY

Participation in this study may provide potential benefits, including improvement in physical conditioning as expected from a structured exercise program recommended by major international cardiology societies. However, it is also possible that you may not derive any direct benefit from participating in the study.

To date, no adverse events related to exercise have been observed in our supervised rehabilitation program. Rare potential side effects may include dizziness, changes in blood pressure (either increases or decreases), and, much less commonly, cardiac rhythm disturbances such as arrhythmias.

ALTERNATIVE TREATMENTS/PROCEDURES

Since you are unable to participate in a supervised rehabilitation program, there is no alternative to this remote rehabilitation program. Of course, you may continue with standard clinical follow-up at the Cardiology Day Hospital if you wish.

CONFIDENTIALITY AND ETHICS COMMITTEE

The sponsor or Principal Investigator of this study ensures that the processing, communication, and transfer of personal data of all study participants will comply with **Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los derechos digitales** and its implementing regulations approved by **Real Decreto 1720/2007 of December 21**. Compliance with these regulations will be monitored throughout the study.

In accordance with these regulations, participants have the right to access, correct, object to, or request deletion of their personal data. Requests should be addressed to the study medical staff, either in person or via email at **icavanzadaytrasplante.hpth@salud.madrid.org**.

Your study-related data will be collected and securely stored in the **RedCap** platform, which is widely validated in biomedical research. Data collected for this study will be identified using a unique code. Only the study personnel and the Clinical Research Ethics Committee will be able to link these data to you or your medical record, when necessary to verify study information or procedures. Confidentiality will be ensured at all times in accordance with applicable law.

Results from this study may be published in scientific journals or presented at medical conferences, without revealing any personal information that could identify you. All collected data will be used exclusively for the purposes described in this document.

If you choose to withdraw your consent to participate in the study, no further information about you will be collected or processed, and no additional interventions related to the study will be performed. Data and samples collected up to the point of withdrawal will not be automatically deleted and may still be used if already analyzed. However, you have the right to request the destruction or anonymization of any unanalyzed data and all previously retained identifiable samples. To exercise this right, please contact the study medical team via the email address provided above.

Please note that the mobile application to be installed on your device has medical device certification and strictly complies with data protection legislation.

FINANCIAL COMPENSATION
Participation in this study does not involve any financial compensation.

INFORMED CONSENT FORM

Study Title: EFFICACY AND SAFETY OF A HYBRID CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH LONG-TERM MECHANICAL VENTRICULAR ASSIST DEVICES: A PILOT STUDY (REHAB-ASSIST)

I,……(Full name of participant)

- I have read the information sheet provided to me.
- I have had the opportunity to ask questions about the study.
- I have received sufficient information about the study.

I have spoken with …… (Full name of the investigator)

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1. At any time.
2. Without providing any explanation.
3. Without this affecting my medical care.

I freely give my consent to participate in this study and my permission for access to and use of my data under the conditions detailed in the information sheet.

I will receive a signed and dated copy of this document.

Participant Name: _____

Date: ____ / ____ / _____

Signature: _____

Investigator Name: _____

Date: ____ / ____ / _____

Signature: _____

WITHDRAWAL OF CONSENT

I, _____ (participant's name),
hereby withdraw my previously given consent and declare my decision to discontinue participation in the study:

Participant Signature: _____
Date: ____ / ____ / _____

Investigator Signature: _____
Date: ____ / ____ / _____